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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,576	05/25/2000	DAPHNA HAVKIN-FRENKEL	13253-00001	5251

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JANET E. REED, ESQ.
WOODCOCK WASHBURN, LLP
ONE LIBERTY PLACE
46TH FLOOR
PHILADELPHIA, PA 19103

EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/27/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/462,576	HAVKIN-FRENKEL ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,10 and 31-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10 and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 8, 2002 has been entered.

Claims 35-40 have been cancelled.

Claims 1, 6, 9, 10, 31 and 32 have been newly amended.

Claims 1-7, 9-10 and 31-34 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 9-10, 31-32 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to cultured *Vanilla planifolia* cells, including embryo and root cells, produced by the method of claim 1, wherein at 15 days in culture the cells produce at least twice as much or tens times as much vanillin as unsupplemented cells cultured 15 days under equivalent conditions.

The claimed invention lacks written description under current written description guidelines. The claim is drawn to cultured *Vanilla planifolia* cells whose sole identifying characteristic is the amount of vanillin produced when cultured according to the claimed methods. The amount of vanillin produced when cultured according to the claimed methods is not a sufficient relevant identifying characteristic in and of itself as the amount of vanillin produced by cultured *Vanilla planifolia* cells is known to be variable. If the claimed *Vanilla planifolia* cells themselves cannot be identified by sufficient relevant identifying characteristics clearly disclosed in the specification, then it would be impossible to determine whether or not *Vanilla planifolia* cells of unknown origin are covered by the claim. Thus *Vanilla planifolia* cells which are not disclosed by sufficient relevant identifying characteristics are not considered to be possessed by Applicant. Absent further guidance, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine whether a *Vanilla planifolia* cell has been produced solely by the claimed methods. Accordingly, there is a lack of written description for the claimed cells, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 1-7, 9-10 and 31-34 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing vanillin in cultured *Vanilla planifolia* cells by supplementing the culture with 3% malic acid alone, 1 mM 3,4-dihydroxybenzaldehyde alone, or 30 ug/mL glycosylated lysozyme elicitor protein alone, does

not reasonably provide enablement for a method for producing vanillin in cultured *Vanilla planifolia* cells by supplementing the culture with other combinations of compounds or other supplements, for the reasons of record set forth in the office action mailed June 3, 2002.

Applicant's arguments filed November 8, 2002, have been fully considered but they are not persuasive.

Applicants argue that the claims as amended are fully enabled, as the particular culture supplementations and combinations recited in the claims are specifically set forth in Examples 3-5 of the specification, and ranges of the amounts of the supplements are also set forth in the Examples and elsewhere in the specification (reply pages 6-7).

The Examiner maintains that while the particular culture supplementations and combinations recited in the claims are set forth in the specification, and ranges of the amounts of the supplements are also set forth in the specification, the effect of the particular culture supplementations and combinations on vanillin production is not set forth in the specification, and the effect of the ranges of the amounts of the supplements on vanillin production is not set forth in the specification. Example 5, Results of Selected Feeding Experiments (pages 26-29), merely states that the experiments for which the results are reported are from experiments "performed in accordance with the procedures set forth in Examples 1-4" (page 26 lines 6-7). The results set forth in Table 1 show the results of experiments testing the effect of vanillin precursors on vanillin production by vanilla embryos, but the results can only be correlated with the supplementation of the culture with 1 mM 3,4-dihydroxybenzaldehyde alone (page 26). The results in Table 1 are not specifically correlated with the particular culture supplementations and combinations recited in the claims, or the ranges of the amounts of the supplements recited in the

claims. Similarly, the results set forth in Table 5 show the results of experiments testing the effect of glycosylated lysozyme elicitor proteins on vanillin production by vanilla embryos, but the results can only be correlated with the supplementation of the culture with 30 ug/mL glycosylated lysozyme elicitor protein alone (page 29). The results in Table 5 are not specifically correlated with the particular culture supplementations and combinations recited in the claims, or the ranges of the amounts of the supplements recited in the claims. Likewise, the results set forth in Table 6 show the results of experiments testing the effect of 3% malic acid on vanillin production by vanilla embryos, but the results can only be correlated with the supplementation of the culture with 3% malic acid alone (page 29). The results in Table 6 are not specifically correlated with the particular culture supplementations and combinations recited in the claims, or the ranges of the amounts of the supplements recited in the claims.

Claim Rejections - 35 USC § 102

Claims 9-10, 31-32 and 34 remain rejected under 35 U.S.C. 102(b) as being anticipated by Knuth et al (US 5,057,424, 15 October 1991, Applicant's IDS), for the reasons of record set forth in the office action mailed June 3, 2002.

Applicant's arguments filed November 8, 2002, have been fully considered but they are not persuasive.

Applicants assert that the subject matter of the amended claims is not identically disclosed by Knuth et al., as the claims now recite the limitation that, at 15 days following the initiation of the supplementation, the cells or cultures produce at least twice as much vanillin as

do cells or cultures not subject to supplementation, said limitation not being disclosed by Knuth et al. (reply pages 7-8).

The Examiner maintains that Knuth et al., or any reference teaching *Vanilla planifolia* cells, anticipates the claimed invention, regardless of claim limitations referring to the method by which such cells are treated or prepared, as the cells taught by Knuth et al. would be indistinguishable from the claimed cells. See In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Knuth et al (US 5,057,424, 15 October 1991, Applicant's IDS).

The claims are drawn to a method for producing vanillin in cultured *Vanilla planifolia* comprising providing a tissue culture of *Vanilla planifolia* and supplementing the culture with malic acid in an amount effective to result in vanillin production, including malic acid at a concentration of 0.01% and 5% by weight of the culture medium.

Knuth et al. teach a method for producing vanillin in cultured *Vanilla planifolia* comprising providing a cell culture comprising *Vanilla planifolia* cells obtained from root tips, said culture being supplemented with 10 mg/L malic acid (columns 13-14 Example 2). Knuth et al. also teach an increase the production of vanillin by these cells, from 1.8 mg/L to 18 mg/L (column 15 Example 5).

Accordingly, claims 1 and 3 are anticipated by Knuth et al.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
January 19, 2003

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600